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09/852,958

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,958

Applicant(s)

SIRBASKU, DAVID A.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 4-10, 12-86, 95-101 and 109-122 is/are pending in the application.
- 4a) Of the above claim(s) 4-10, 12-33, 44-86, 96-101 and 115-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 34-43, 95 and 109-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/16/02, 4/14/03, 6/
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. The Amendment filed December 27, 2005 in response to the Office Action of March 3, 2005 is acknowledged and has been entered. Previously pending claims 34, 37, 44, 99 have been amended, claim 44 remains withdrawn from consideration for the reasons of record and 99 remains withdrawn from consideration essentially for the reasons of record. In particular, claim 99 remains withdrawn from consideration because although it now depends from claim 34, it is drawn to a method comprising detecting an anti-estrogenic substance which is a method which was previously restricted from the claimed invention. Claims 34-43, 95 and 109-114 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 34-43, 95, 109-114 remain rejected under 35 USC 112, second paragraph for the reasons previously set forth in the action mailed on March 3, 2005, Section 11, pages 7-8.

Applicant argues that steroid-hormone-like would be interpreted by even a minimally skilled artisan to include those agents that have an effect on cells similar to those of steroid hormone. The argument has been considered but has not been found persuasive because Applicant does not address the issue raised, that is, that the term steroid-hormone-like is a relative term and the metes and bounds of the claimed "likeness" cannot be determined.

Applicant further cites the specification at paragraph 0049 and argues that given the teaching of the specification the skilled artisan could take well-known steroid responsive cells and growth them to determine "a steroid-like" effect on the

cells. The argument has been considered but has not been found persuasive because, once again, Applicant does not address the issue raised, that is, that the term steroid-hormone-like is a relative term and the metes and bounds of the claimed “likeness” cannot be determined.

Applicant argues that the specification teaches assays to test compounds that might possess steroid hormone-like cell growth stimulating (“steroidogenic”) effects. The argument has been considered but has not been found persuasive because, once again, Applicant does not address the issue raised, that is, that the term steroid-hormone-like is a relative term and the metes and bounds of the claimed “likeness” cannot be determined.

Applicant states that a GOOGLE search reveals 219 hits drawn to “steroid hormone-like” and GOOGLE SCHOLAR discloses at least 14 scientific publications with the exact phrase and argues that given the GOOGLE searches, it is clear that the scientific community understands and uses the phrase with some regularity. The argument has been considered but has not been found persuasive because, as previously set forth the art recognizes, as set forth in US Patent No. 5,135,849 that the term “androgenic” has no well defined meaning in the art and is conventionally used inconsistently and indiscriminately and US Patent No. 4,859,585 specifically teaches that the term “estrogenic” has no well defined meaning in the art and is conventionally used inconsistently and indiscriminately. Given that there is no art recognized definition for the terms, both of which read on the claimed phrase “steroid hormone-like”, it is clear that the exact meaning of the term “steroid hormone-like” is not known and the claims are indefinite for the reasons of record.

Applicant argue that the inventors of US Patent No. 5,135,849 refers to agents that have a “hormone-like effect” in a post-filing paper, published twelve years after the priority date of the ‘849 patent. The argument has been considered but has not been found persuasive because the paper was not submitted and therefore the information therein cannot be evaluated.

Applicant argues that at least 15 patents have been issued that include the term “hormone-like”. The argument has been considered but has not been found persuasive because as Applicant must be aware, each patent application is examined on its own merits and for the reasons of record, the instantly claims do not meet the requirements of 35 USC 112, second paragraph.

Applicant argues that the skilled artisan recognizes the term “substance of interest”. The argument has been considered but is somewhat confusing since Examiner was unable to find a rejection under 35 USC 112, second paragraph drawn to the phrase “substance of interest”.

Applicant argues, as drawn to the term “substantially devoid” that the use of imprecise language does not automatically render a claim invalid for indefiniteness and when a term of degree such as substantially is used in a claim, then the court must determine whether the specification provides some standard for measuring that degree. The argument has been considered but has not been found persuasive because although it is clear that Examiner is not the Court, it is equally clear that the specification provides no standard for measuring the degree. Applicant might be interested in reviewing MPEP 2173.05(r) which is drawn to Omnibus claims which recite the term “substantially”. The MPEP instructs that these claims should be rejected under 35 U.S.C. 112, second paragraph, because they are indefinite in that they fail to point out what is included or excluded by the claim language. The

fact pattern here is identical to the fact pattern disclosed in MPEP 2173.05r in that in the instant use of the term “substantially”, the claims fails to point out what is included or excluded

Applicant's arguments have not been found persuasive and the rejection is maintained.

5. Claims 34-39, 41-43, 95, 109-114 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the action mailed on March 3, 2005, Section 12, pages 8-15.

Applicant argues that the arguments and evidence set forth about drawn to the indefiniteness rejection are incorporated herein. The arguments have been considered above and have not been found persuasive for the reasons set forth above.

Applicant argues that the specification provides extensive discussion, examples, figures and data to support the enablement for the method claims at issue. The argument has been considered but has not been found persuasive because, for the reasons of record, neither the specification nor the art of record enable the invention as broadly claimed.

Applicant argues that the issue at question herein is that the method claims are used to examine substances of interest, support for which has been discussed above. The argument has been considered but has not been found persuasive because, for the reasons of record, neither the specification nor the art of record support enable the invention as broadly claimed.

Applicant argues that *Rochester v. Searle* is inapposite to the present claims because the instant issue is drawn to method claims, wherein several examples of the immunoglobulin inhibitors that may be used with the method are taught and

their effects clearly demonstrated. Since steroid-like effects and agents are well known, the method of the present invention clearly provides enablement for a method of screening for agents with these steroid-like effects in conjunction with the novel immunoglobulin inhibitors. The argument has been considered but has not been found persuasive since, as set forth above, the claims as drawn to the term “steroid-hormone like” are indefinite and further because, for the reasons set forth previously, the claims are not enabled for the broadly claimed invention, wherein only “novel” immunoglobulin inhibitors are taught and the specification clearly teaches that numerous immunoglobulins do not act as immunoglobulin inhibitors that inhibit cell growth in the absence of an inhibition-reversing amount of steroid hormone. Further, Applicant mischaracterizes the rejection since *Rochester v. Searle* was not cited in regard to the claimed method, but rather in regard to the broadly claimed immunoglobulin inhibitors. Further, it is noted that this grounds of rejection does not rest on the *Rochester v. Searle* case-law.

Applicant further argues that no agents with steroid-like effects have been claimed as was the case with the claims at issue in *Rochester v. Searle*. The argument has been considered but has not been found persuasive since the issue raised is not drawn to the claimed agents, but rather is drawn to the broadly claimed immunoglobulin inhibitors.

Applicant argues that what is well-known is best omitted from the specification and that all that is necessary is that one skilled in the art be able to practice the claimed invention. Given the level of knowledge and skill in the art and in the present invention, the key enabling agent is the inhibitory immunoglobulin that enables the method that is used to examine the potential substance of interest. The arguments have been considered and have not been

found persuasive. The rejection is not drawn to the identified novel immunoglobulin inhibitors, but to the scope of the claims for the reasons set forth previously and above. Further, the omitted information is not well-known or even known in the art and one skilled in the art is not able to practice the invention as broadly claimed because neither the specification nor the art of record provide sufficient guidance to enable the scope of the claims. Applicant is correct. The key enabling agent is the inhibitory immunoglobulin and for the reasons of record, none of the originally filed specification, claims or art of record enable the broadly claimed invention.

Applicant points out that Examiner makes the assumption that because data was not shown for IgG2-kappa and that its discussion was not followed up in the Example 23, that somehow its effect was not significant. Applicant disagrees with Examiner's assumption and argues that the best evidence of the meaning of the specification is the specification itself wherein Applicant points to the teachings wherein the invention is reduced to practice. The argument has been considered but has not been found persuasive because, for the reasons of record, the broadly claimed invention is not enabled. Further, as drawn to IgG2-kappa, although Applicant disagrees with Examiner's assumption and points to the specification as the best evidence of the meaning of the specification, it is clear that the specification is ambiguous at best. One might wonder why, given Examiner's clear questioning of the information in the specification, Applicant did not simply submit objective evidence demonstrating the efficacy of IgG2-kappa if such efficacy exists.

Applicant points to pages 12-13 and asks the office if it has caselaw to present that supports the statement that "one cannot extrapolate from the

specification to the enablement of the claims”. Further, Applicant stands ready to traverse and address any such caselaw. The request has been noted but Examiner is not clear as to why Applicant is asking for citations of case law to support a statement conventionally used in patent prosecution.

Applicant argues that Applicant has no preference for Fc receptor and all equivalent Fc receptors fall within the scope of the claims. The argument has been considered but has not been found persuasive because it is unknown what “equivalent Fc receptors” might be and Applicant is not addressing the issue raised. The issue raised is not that the exact nature and structure of any particular Fc receptor must be provided but that the surprising identification of three immunoglobulins that are useful in the claimed invention does not predictably enable the broadly claimed invention because the specification does not teach how to make the claimed invention. Examiner simply points out that the absence of guidance as to the receptors that effective immunoglobulins bind is a defect of the specification because that information might have been used as guidance for predictably identifying the broadly claimed inhibitors.

Applicant argues that methods of isolating immunoglobulin inhibitor in four species are taught and therefore Examiner’s statement on page 14 that in the absence of an effective inhibitor, one would not be able to successfully use the claimed broadly claimed invention is not applicable to the present invention. The argument has been considered but has not been found persuasive because Applicant is mischaracterizing Examiner’s arguments on page 14 which are drawn not only to *Rochester v. Searle* (from which section the isolated quotation is drawn) but also to the lack of teaching in the specification on how to predictably identify other and make other useful steroid reversible immunoglobulin inhibitors.

Applicant argues that, contrary to Examiner's statements, the specification provides 148 figures and 28 examples in 814 paragraphs that support the method as claimed. The argument has been considered but has not been persuasive because none of the 148 figures 28 examples or 814 paragraphs enable the broad scope of the claimed invention.

The arguments have been considered but have not been found persuasive for the reasons set forth above and the rejection is maintained.

It is further noted that Applicant did not address the issues drawn to (1) the surprising nature of the discovery upon which the invention is based, (2) the fifteen year search for serum borne inhibitors of steroid responsive cell growth, (3) the lack of guidance in the specification as how to predictably identify other useful steroid reversible inhibitors, (4) how to distinguish tissue inhibitory immunoglobulins from those that are not inhibitory.

6. Claims 34-39, 41-43, 95, 109-114 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the action mailed on March 3, 2005, Section 13, pages 15-18.

Applicant argues that the arguments and evidence presented above are also incorporated in the instant response. The arguments and evidence have been considered above and have not been found persuasive for the reasons set forth above.

Applicant argues that Examiner's recitation of *Eli Lilly* and *Enzo* is not appropriate since they are drawn to product cases and the instantly claimed invention is a method. The argument has been considered but has not been found persuasive because Applicant appears to misunderstand the issue raised. The issue raised is that not that there is no adequate written description of the method, but

rather, like the products of *Eli Lilly* and *Enzo*, there is no adequate written of products critical to the method claimed. In the absence of a written description of critical elements, the method claims lack adequate written description.

Applicant requests that Examiner cite case law to support the written description rejection. The request has been considered and Examiner suggests that Applicant review the action mailed on March 3, 2005, Section 13, pages 15-18 wherein case law that supports the written description rejection is cited.

Applicant argues that the claims presently at issue are method claims that may be used to test “substances of interest” A phrase that was established and has received the imprimatur of the office and challenges the office to withdraw any patent using the phrase from issue if case law is not produced. The argument has been considered but it appears that Applicant has not carefully read the rejection set forth in Section 13 since the rejection is drawn to the broadly claimed immunoglobulin inhibitors and not to “substances of interest”.

Applicant argues that specific examples have been identified and therefore the specification provides an adequate written description. The argument has been considered but has not been found persuasive for the reasons of record.

Applicant presents arguments drawn to Examiner’s discussion of a possible amendment of the claims. The arguments are moot given that the possible amendment was not made.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC 112

7. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is indefinite because it recites the phrase “said immunoglobulin inhibitors”. The claim is indefinite because there is no antecedent basis for the claimed limitation in claim 34 from which claim 37 depends since claim 37 is drawn to “an isolated immunoglobulin inhibitor” which is reasonably interpreted as a single immunoglobulin inhibitor. Amendment of claim 37 to delete the term “inhibitors” and substitute therefore the term “inhibitor” would obviate the instant rejection.

8. No claims allowed.

9. All other objections and rejections set forth in the previous Office Action are hereby withdrawn.

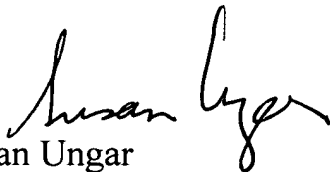
10. Applicant’s amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY

PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish at the end.

Susan Ungar
Primary Patent Examiner
June 7, 2006